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Note verbale dated 24 March 2002 from the Permanent Mission of Brazil to the United Nations Office at Geneva addressed to the Chairperson of the fifty-eighth session of the Commission on Human Rights

The Permanent Mission of Brazil to the United Nations Office and other International Organizations in Geneva presents its compliments to Ambassador Krzysztof Jakubowski, Chairman of the fifty-eighth session of the Commission on Human Rights, and has the honour to forward herewith a copy* of the Brazilian Government's written comments on the implementation of Commission resolution 2001/33, entitled "Access to medication in the context of pandemics such as HIV/AIDS".

The Permanent Mission of Brazil would like to request that these written comments be circulated as an official document of the fifty-eighth session of the Commission on Human Rights and to be inserted on the web site of the Office of the High Commissioner for Human Rights accordingly.

* Reproduced as received, in English only.

Introduction

The year 2001 represents a landmark in the fight against the HIV/AIDS epidemic worldwide. For the first time ever the United Nations General Assembly convened a Special Session to deal with, in a comprehensive manner, the disease that has already killed more than 22 million people since it was identified in the early 1980s and currently infects another 36 million in all continents. The voice of the world society, however, is not restricted to the UNGASS on HIV/AIDS, which was held from 25-27 June 2001 in New York. On the contrary, a plurality of documents, resolutions, statements and others have been produced on a year that witnessed the rise of a rich and lively debate on HIV/AIDS, specially in what concerns the capacity of countries to provide their populations with the means necessary to treat those infected and affected by the disease. A wide range of interrelated concerns were also brought up in the international agenda, involving mainly issues of human rights, patents, access to life-saving anti-aids medicines and the World Trade Organization-based Agreement on Trade-Related Intellectual Property Rights (TRIPS). All of this has served to a very important purpose: to create a solid normative as well as reasonable background against which countries can envision and design far-reaching and all-inclusive national responses to the HIV/AIDS epidemic.

Resolution 2001/33, entitled "Access to Medication in the Context of Pandemics such as HIV/AIDS", approved on the 23rd of April 2001 by occasion of the 57th Session of the United Nations Commission for Human Rights, is by far one of the major contributions the international community managed to come up with during the current year in the field of HIV/AIDS. It symbolized a key breakthrough in the apparent and false dichotomy between efforts directed at prevention and those aimed at treatment and care for those already infected. It unveiled a whole territory where governments had been insofar timid to walk in – the duty to provide medicines to all those in need – and helped to unleash the call for action that was later approved unanimously by the UNGASS on HIV/AIDS through its Declaration of Commitment.

Issues Under Consideration

The cornerstone progress of Resolution 2001/33 is the clear and unambiguous acknowledgement of access to medication in the context of pandemics – such as HIV/AIDS – as an integral and primary element of any strategy that seeks to guarantee the enjoyment of everybody's right to the highest attainable standard of physical and mental health, recognized worldwide as a fundamental human right. In other words, it is impossible to protect everyone's right to the highest attainable standard of physical and mental health without public policies that ensure the provision of life-saving medicines to all those in need.

Brazil was a major contributor and sponsor of Resolution 2001/33, not only because of its understanding of the importance of treatment and care in the battle against HIV/AIDS, but also, and mainly, because of its principled commitment to the protection and advancement of the human rights of those people living with HIV/AIDS (PLWA) and because of its comprehension that the deep involvement of PLWAs enhances and maximizes the capacity of the State to play a meaningful role in the overall strategy to halt the AIDS epidemic.

Resolution 2001/33, however, enshrined in its clauses not only normative principles but also pragmatic steps that ought to be taken so as to ensure all pledges in it can be fully met. What

follows is an attempt to inform, in a summarized manner, what Brazil has been doing in this field so as to live up to its vows.

Brazil and Access to Medicines – the HIV/AIDS case

Brazil is one of the few developing countries that provide free and universal distribution of anti-retrovirals to every single HIV+ patient that seeks assistance in the public health system. This policy was started in the early 90s, with the distribution of AZT and was rapidly expanded in the ensuing years. It evolved on a very steady manner until November 1996, when the Congress passed a law making it an obligation of the State to provide anti-aids drugs to the population. In real terms it did not affect much of the policy under implementation, but it strongly boosted the support for and legal stance of the National AIDS policy.

Brazil currently distributes 14 antiretroviral drugs of 3 pharmacological classes to all HIV infected patients that meet the criteria set down by national guidelines, which are designed by expert committees assembled annually to review practices as well as new technical progresses worldwide. Of the aforementioned 14 drugs, eight are locally-produced anti-retroviral formulations, with pharmacological specifications for generic versions of these groups. Approximately one hundred and ten thousand patients are currently under antiretroviral treatment freely distributed through the Brazilian public health system and roughly three hundred million dollars were spent in 2000 alone on purchasing the drugs that make up the so-called 'anti-HIV cocktail'.

Resolution 2001/33 also calls upon countries to assure that the pharmaceutical or medical technologies used to treat HIV/AIDS are scientifically and medically appropriate and of good quality. In Brazil, the quality control of the antiretrovirals distributed by the Ministry of Health is done by: (1) mandatory statement from the competent health authority in the country of manufacture, certifying that the plant complies with the Good Manufacturing Practices (GMP); (2) preliminary inspection of the pharmaceutical plant before the first delivery of the product; (3) monitoring of the production of the first batches; (4) in the early phases of the procurement contract, analysis of batches purchased at laboratories accredited by the National Health Surveillance Agency from the Ministry of Health and (5) bioequivalence testing.

On the long term, however, given the increasing number of patients needing more expensive, complex treatments, such a path of action would prove unsustainable, for it would strip the Government of the adequate funding necessary to keep it on track. Hence, in order to expand the access to antiretroviral therapy on a sustainable manner, it is crucial to look for ways and means of lowering the sky-rocketing high prices of aids drugs. Some strategies have been successfully used by the Brazilian Government to this end. In fact, the price of antiretroviral drugs purchased by the Brazilian Ministry of Health has been declining quite significantly over the last few years. This is mainly thanks to, firstly, investments made by the Ministry of Health to set up national State laboratories and, secondly, effective negotiation of drug prices with those pharmaceutical drug companies that are exclusive producers of certain anti-AIDS drugs. The average cost for patient/year in antiretroviral therapy decreased a full 48% between 1997 and 2001 ($US 4,860 in 1997 to $US 2,530 in 2001).

It is, therefore, apparent that Brazil has measured no efforts in order to ensure the availability in sufficient quantities and at affordable prices of pharmaceuticals and medical technologies used to treat HIV/AIDS. The National STD/AIDS Coordination, the federal-level arm of the Brazilian response, is responsible for harmonizing and organizing the actions of dozens of regional agencies, NGOs and countless field experts, fostering an improved collective approach. It is counseled by several *advisory expert committees*, and public policies are implemented taking into due account the vast number of diverse social realities that reflect and include the most vulnerable sectors of the population. Special preventive actions targeted at women, youths, children, mobile populations, injecting drug users, truck drivers, men who have sex with men etc are commonplace and have been under implementation for some time now. Particular measures to reduce stigma, silence, discrimination and denial of and against people living with HIV/AIDS have also been put into practice and have yielded impressive results.

Resolution 2001/33 further calls upon States to adopt legislation or other measures, in accordance with international law, to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies. In fact, there are still around 85 law projects related to the STD/HIV/AIDS issue that are waiting for review and approval at the Brazilian Congress. Matters covered range from care and treatment to education, guarantee of fundamental human, labor and social rights, tax and criminal law, prevention and communication strategies and harm reduction behavioral interventions.

At the international level, Resolution 2001/33 calls upon the international community to continue to assist the developing countries in their fight against pandemics such as HIV/AIDS. Brazil has also been actively working so as to foster and expand access to aids-related medicines in the neediest developing countries, specially in Africa and Latin America and the Caribbean. In this respect, international cooperation projects supported by Brazil seeks to cover three key points: technology transfers for local manufacture and quality control of ARV drugs; training for building infrastructure required for care and treatment; and the creation of an International AIDS Drugs Data Bank. These project include, but are not restricted to, all Portuguese-speaking African countries and dozens of Latin American nations, which make up the so-called Horizontal Technical Cooperation Group, the HTCG.

The Brazilian Government has also been pushing, at the World Trade Organization, a flexible interpretation of the TRIPS Agreement so as to make sure nothing in it prevents Members from taking measures to protect public health, particularly in crisis of a magnitude such as the HIV/AIDS one. It is indeed beyond doubt that such a position is necessary in order to fulfill the pledge, included in Resolution 2001/33, of taking into due account the right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the negotiations under way in international bodies, of which the World Trade Organization is no exception.

Along with this policy, Brazil has also been advocating the principle of differential pricing as a key part of its strategy to widen access to medicines in developing countries. It is based on the assumption that it is unreasonable and impractical for a country with a low GNP per capita to pay the very same high prices charged in developed markets for the very same drugs. Anti-aids cocktails cost in between 10 to 15 thousand dollars in the developed world, what represents more than ten times the annual per capita income of some of the poorest and hardest

HIV-hit nations in Africa. There are a few indicators available to orient the implementation of differential pricing globally, among which the Human Development Index (HDI), from the United Nations Developing Program (UNDP), is a feasible choice.

Nonetheless, the international community must also financially support the acquisition of such drugs even if these are brought down to much more manageable levels. Impoverished countries cannot take upon the task of treating their populations if they are left without the means to do so. A strong, prosperous and resourceful Global Fund to Fight AIDS, Tuberculosis and Malaria is, therefore, a powerful tool in fulfilling the ultimate objective of Resolution 2001/33.

Conclusion

All this has enabled Brazil to slash its aids-related mortality levels by fifty to seventy per cent. Incidence of opportunistic infections was reduced dramatically. The number of tuberculosis cases, for instance, dropped 80% in the last four years, in the State of Sao Paulo, which carries roughly fifty per cent of all aids cases reported in Brazil. Morbidity has also been deeply reduced, by an average of seventy per cent, avoiding two hundred and thirty four thousand hospitalizations, and saving the impressive amount of seven hundred and eleven million dollars.

However, it must be said that access to medicines is but a feature of the Brazilian national response to the HIV/AIDS epidemic. Its success, in fact, lies upon a concerted early governmental response, a strong and effective participation of the civil society, a multisectoral mobilization, and an integrated approach that draws together prevention, treatment and advocacy of human rights in all strategies and actions. It was this blend of aspects that managed to refute the worst predictions of international advisors, which predicted Brazil would have, by the year 2000, approximately 1.2 million HIV+ patients. Nowadays, the estimated number is half of that, around 597,000.

It is clear, therefore, that Brazil has fully implemented Resolution 2001/33. Still, there is an unambiguous agenda for the future in the fight against the epidemic, particularly in the field of vaccine development, but there are strong signals that the epidemic in Brazil has been nearly brought under control, and, most importantly, the quality of life of HIV+ patients has showed a steady trend upwards.